DEPARTMENT OF HEALTH & HUMAN SERVICES

Public Health Service

Food and Drug Administration
9200 Corporate Boulevard
Rockville MD 20850

MAY 23 2005

Carl Zeiss Meditec AG
c/o Mr. R. Michael Crompton
Vice President, Regulatory/Clinical Affairs and Quality Assurance
Carl Zeiss Meditec Incorporated
5160 Hacienda Drive
Dublin, CA 94568

Re: K043222
Trade/Device Name: Carl Zeiss Meditec AG VISUCAM™ C Digital Camera
Regulation Number: 21 CFR 886.1120
Regulation Name: Ophthalmic Camera
Regulatory Class: Class II
Product Code: HKI
Dated: January 19,2005
Received: January 21,2005

Dear Mr. Crompton:

This letter corrects our substantially equivalent letter dated February 14,2005 regarding the Product Code that was stated incorrectly in the reference block as MKI. The correct Product Code should read HKI.

We have reviewed your Section 510(k) premarket notification of intent to market the device referenced above and have determined the device is substantially equivalent (for the indications for use stated in the enclosure) to legally marketed predicate devices marketed in interstate commerce prior to May 28, 1976, the enactment date of the Medical Device Amendments or to devices that have been reclassified in accordance with the provisions of the Federal Food, Drug, and Cosmetic Act (Act) that do not require approval of a premarket approval (PMA). You may, therefore, market the device, subject to the general controls provisions of the Act. The general controls provisions of the Act include requirements for annual registration, listing of devices, good manufacturing practice, labeling, and prohibitions against misbranding and adulteration.

If your device is classified (see above) into either class II (Special Controls) or class III (PMA), it may be subject to additional controls. Existing major regulations affecting your device can be found in the Code of Federal Regulations, Title 21, Parts 800 to 898. In addition, FDA may publish further announcements concerning your device in the Federal Register.

Please be advised that FDA's issuance of a substantial equivalence determination does not mean that FDA has made a determination that your device complies with other requirements of the Act or any Federal statutes and regulations administered by other Federal agencies. You must comply with all the Act's requirements, including, but not limited to: registration and listing (21 CFR Part 807); labeling (21 CFR Part 801); good manufacturing practice requirements as set forth in the quality systems (QS) regulation (21 CFR Part 820); and if applicable, the electronic product radiation control provisions (sections 531-542 of the Act); 21 CFR 1000-1050.

This letter will allow you to continue marketing your device as described in your Section 510(k) premarket notification. The FDA finding of substantial equivalence of your device to a legally marketed predicate device results in a classification for your device and thus, permits your device to proceed to the market.

If you desire specific advice for your device on our labeling regulation (21 CFR Part 801), please contact the Office of Compliance at (240) 276-8910. Also, please note the regulation entitled, "Misbranding by reference to premarket notification" (21CFR Part 807.97). You may obtain other general information on your responsibilities under the Act from the Division of Small Manufacturers, International and Consumer Assistance at its toll-free number (800) 638-2041 or (301) 443-6597 or at its Internet address http://www.fda.gov/cdrh/dsma/dsmamain.html

Sincerely yours,

David M. Whipple
Acting Director
Division of Ophthalmic and Ear,
Nose and Throat Devices
Office of Device Evaluation
Center for Devices and
Radiological Health

Statement of Indications for Use

510(k) Number (if known): K043222

Device Name: VISUCAM™ C Digital Camera

Indications for Use: The VISUCAM C Digital Camera is intended for photographing, displaying and storing the data of the retina and surrounding parts of the eye to be examined under mydriatic and non-mydriatic conditions. These photographs support the diagnosis and subsequent observation of eye diseases which can be visually monitored and photographically documented.

(PLEASE DO NOT WRITE BELOW THIS UNE-CONTINUE ON ANOTHER PAGE I F NEEDED)

Concurrence of CDRH, Office of Device Evaluation (ODE)

(Division Sign-Off)
Division of Ophthalmic Ear,
Nose and Throat Devises

510(k) Number K043222

Prescription Use ✓ OR Over-the-Counter Use_____
(Per 21 C.F.R. § 801.109)

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K043222

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510(k) Summary
Carl Zeiss Meditec AG

VISUCAM C™ Digital Camera

This 510(k) summary for the VISCUCAM C™ Digital Camera is submitted in accordance with the requirements of SMDA 1990 and 21 CFR 807.92.

GENERAL INFORMATION

Manufacturer:
Carl Zeiss Meditec AG
Carl Zeiss Promenade 10
07740 Jena
Germany
Est. Reg. No. 9615030

Contact Person:
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RA-Manager

U.S. Designated Agent:
R. Michael Crompton
Vice President, RA/CA/QA
Carl Zeiss Meditec Inc.
5160 Hacienda Drive
Dublin, California 94568
(925) 557-4353 (phone)
(925) 557-4481 (fax)

DEVICE DESCRIPTION

Classification: Class II

Trade Name: VISCUCAM C™ Digital Camera

Generic/Common Name: Ophthalmic Camera, AC-powered (21 CFR § 886.1120)

PREDICATE DEVICE

(1) VISUCAM^{LITE}™ Fundus Camera (K021787)
(2) Canon Non-Mydriatic Retinal Camera, Model CR6-45NM (K980246)

INTENDED USE

The VISUCAM C Digital Camera is intended for photographing, displaying and storing the data of the retina and surrounding parts of the eye to be examined under mydriatic and non-mydriatic conditions. These photographs support the diagnosis and subsequent observation of eye diseases which can be visually monitored and photographically documented.

DEVICE DESCRIPTION

The VISCUCAM C™ Digital Camera is intended to capture, display and store images of the eye, especially the retinal area, as well as surrounding areas, to aid in diagnosing or monitoring diseases of the eye that may be observed and photographed. The VISCUCAM C™ Digital Camera is indicated for use in both mydriatic and non-mydriatic modes. As such, it incorporates appropriate light sources and filters so that images can be captured under both mydriatic and non-mydriatic conditions.

SUBSTANTIAL EQUIVALENCE

The VISCUCAM C™ Digital Camera is substantially equivalent to the VISUCAM^{LITE}™ Fundus Camera (K021787) and the Canon Non-Mydriatic Retinal Camera, Model CR6-45NM (K980246). All three devices are intended to capture images of the eye and incorporate features, such as light sources and filters, in order to function in accordance with their respective intended uses.

CONCLUSION

As described in this 510(k) Summary, all testing deemed necessary was conducted on the VISCUCAM C™ Digital Camera to ensure that the device is safe and effective for its intended use when used in accordance with its Instructions for Use.